

# Exhibit 16

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION  
OPIATE LITIGATION

This document relates to:

*The County of Summit, Ohio, et al. v. Purdue  
Pharma L.P., et al.*

Case No. 18-op-45090

*The County of Cuyahoga, Ohio, et al. v. Purdue  
Pharma L.P., et al.*

Case No. 17-op-45004

MDL No. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**EXPERT REPORT OF SEAN NICHOLSON, PH.D.**

May 10, 2019

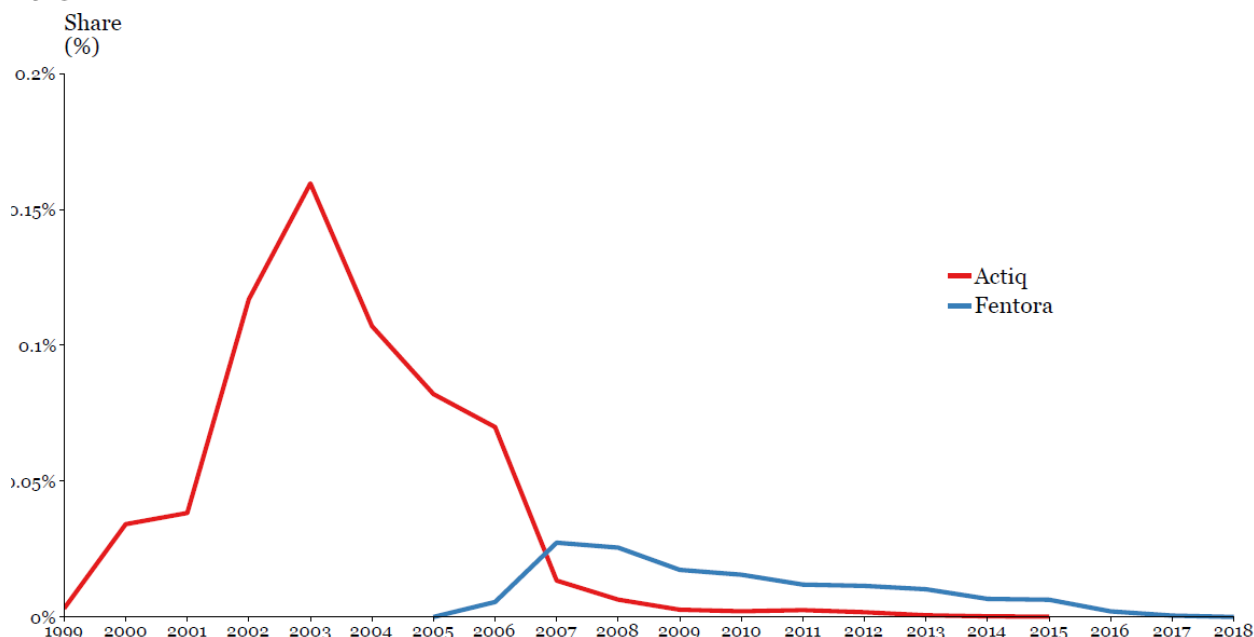
## **1. QUALIFICATIONS**

1. I am a Professor in the Department of Policy Analysis and Management and the Director of the Sloan Program in Health Administration at Cornell University. I am also a Research Associate at the National Bureau of Economic Research. Prior to joining Cornell, I served as an Assistant Professor in Health Care Systems at the Wharton School of the University of Pennsylvania. I have a Ph.D. in economics from the University of Wisconsin-Madison and an A.B. in economics from Dartmouth College. My research and teaching specialty is the economics of health care. My curriculum vitae, including a list of publications, is attached as Appendix A.

2. In my academic career, I have researched the economics of the health care industry, with an emphasis on the biotechnology and pharmaceutical sectors. In this field of study, I have published articles in leading academic journals and presented my research at academic conferences. In addition, I have served as a principal investigator on research projects sponsored by the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Robert Wood Johnson Foundation, and by leading pharmaceutical companies.

3. My research projects have included identifying what types of firms are most effective at developing drugs, assessing risk in the health care industry, and determining the value of new medical technologies. I have done extensive research on the risks and uncertainties facing pharmaceutical companies. I have also conducted research and offered expert testimony in multiple cases in the pharmaceutical industry. Appendix B contains a list of cases in which I have provided deposition or trial testimony in the last four years.

4. I am being compensated at my standard billing rate of \$850 per hour. I have been assisted in this matter by staff of Cornerstone Research, who worked under my direction. I receive compensation from Cornerstone Research based on its collected staff billings for its support of me in this matter. Neither my compensation in this matter nor my compensation from Cornerstone Research is in any way contingent or based on the content of my opinion or the outcome of this or any other matter.

**EXHIBIT 2****Actiq and Fentora share of opioid prescriptions for Summit and Cuyahoga counties, 1999 – 2018**

Source: IMS Xponent (ALLERGAN\_MDL\_02485011; ALLERGAN\_MDL\_03281086; ALLERGAN\_MDL\_0330303; ALLERGAN\_MDL\_03320305); HUD-USPS ZIP Crosswalk, Q3 2018

Note: Shares are calculated using all records for opioids in IMS Xponent Data. Drugs are labeled as Actiq or Fentora if the product group description contains Actiq or Fentora. Prescriptions are apportioned to counties based on the percent of businesses in a zip code that fall within each county; if the total percent of businesses for a zip code is zero, the percent of all addresses is used. Actiq's market share peaked in 2003 with 0.16 percent, and Fentora's market share peaked in 2008 with 0.03 percent.

**6.2. Consistent with industry practice, Teva USA and Actavis Generic Defendants' promotional spending on generic opioids was minimal and limited to the pricing and commercial availability of those medicines**

44. As Dr. Chintagunta's analysis shows, Teva USA and Actavis Generic Defendants' promotional spending on generic opioids was minimal. In particular, he analyzes Dr. Rosenthal's IQVIA data and finds that Teva USA and Actavis Generic Defendants did not incur any promotional spending for 8 of their 14 generic opioid drugs. Additionally, Dr. Chintagunta finds that between January 1995 and May 2018, Teva USA and Actavis Generic Defendants' marketing spending on their Schedule II generic opioid drugs made up less than 0.09 percent of the combined marketing spending by all manufacturers of Schedule II branded and generic opioids.<sup>71</sup>

45. Furthermore, Christine Baeder, Teva USA's Chief Operations Officer for U.S. Generics, noted in her deposition testimony that for Teva USA's "promotion" for its generics drugs is limited to providing information on pricing and "product availability."<sup>72</sup> She also stated that

<sup>71</sup> Chintagunta Report, Section V.C.

<sup>72</sup> Deposition of Christine Baeder, January 24, 2019 ("Baeder Deposition"), p. 417:2–5.

Teva USA does not promote its generic medications, including generic opioids, either to physicians or patients.<sup>73</sup> Baeder also noted that while Teva USA has a “small marketing budget for generics,” it is “for support of availability messaging, a limited number of journal advertisements around availability messaging, as well as coupons, programs for some limited generic products where it's deemed appropriate.”<sup>74</sup>

46. The same applies to the Actavis Generic Defendants. Several former personnel from the Actavis Generic Defendants testified that they did not promote the safety, efficacy, or therapeutic value of their generic medicines (to physicians or otherwise).<sup>75</sup> For instance, according to Michael Perfetto, former Vice President of Actavis Sales and Marketing, “if you look at generics, we’re all the same product. So we use quality, product supply, and pricing primarily to sell our products.”<sup>76</sup> Andy Boyer, former Senior Vice President of Actavis Sales and Marketing, further added that “it is physically impossible for a generics company to hire enough sales representatives to go in and speak to physicians about all of [their] generics products.”<sup>77</sup> Mr. Boyer also noted that, “We don’t detail products . . . [t]hese are not brands, these are generics. We offer up a price and we offer up a consistent supply in our supply chain and hopefully quality products . . . There’s no pushing, there’s no detailing, there’s nothing else there.”<sup>78</sup>

47. The limited marketing by Teva USA and Actavis Generic Defendants of their generic opioid products is consistent with industry practice. Specifically, generic sales are not typically driven by a generic manufacturer’s marketing efforts. For example, the FDA notes that generic drug manufacturers “generally do not pay for advertising, marketing and promotion,” which in part leads to generics being less expensive than brands.<sup>79</sup> The Federal Trade Commission notes that “brand-name and generic marketing strategies are very different... Brand-name drugs are marketed by emphasizing product differentiation to physicians and consumers and by securing favorable formulary placement with PBMs... By contrast, generic drugs are commodity products marketed to wholesalers and drugstores

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<sup>73</sup> Baeder Deposition, p. 416:5–18.

<sup>74</sup> Baeder Deposition, p. 417:16–24

<sup>75</sup> See, for example, Deposition of Douglas Boothe, January 17, 2019, pp. 146:21–147:10 (Q. Are you aware of what marketing tools were used by Actavis to drive sales of its generic drugs, including opioids, while you were at the company? ... A. ...generic drugs generally don’t do a lot of marketing.”); Deposition of Michael Perfetto, December 18 (“Perfetto Deposition”), 2018, p. 315:11–21 (Q. And what marketing tools did Actavis use to drive sales of these generic products while you were there? A. We – we don’t – we don’t market products. We sell generics. We don’t use marketing. We actually don’t use promotion.”); Deposition of David Myers, December 13, 2018, p. 48:9–11 (“being a generic company, we don’t do major advertising for all products.”); p. 83:6–11 (“Watson [Actavis] did not believe in really advertising generic pharmaceuticals.”).

<sup>76</sup> Perfetto Deposition, pp. 315:22–316:2.

<sup>77</sup> Deposition of Andrew Boyer, January 15, 2019 (“Boyer Deposition”), pp. 316:24–317:7.

<sup>78</sup> Boyer Deposition, pp. 346:9–17.

<sup>79</sup> FDA, “Generic Drugs Undergo Rigorous FDA Scrutiny,” March 27, 2018, available at <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm340343.htm>, accessed on February 14, 2019.

primarily on the basis of price.”<sup>80</sup> Similarly, in its 2017 10-K SEC filing, Teva USA noted that “physicians and patients have little control over the choice of generic manufacturer, and consequently generic medicines are not actively marketed or promoted to physicians.”<sup>81</sup> Indeed, it is the pharmacies that decide which generic drugs to use.<sup>82</sup> This is also consistent with academic research that has shown that physician detailing and product sampling is almost never done for generic products, while journal advertising is occasionally done for generic products, but at a lower rate than for branded products.<sup>83</sup>

48. Rather than relying on marketing, generic drugs generally gain market share over branded drugs primarily through competitive pricing and legislation that encourages the substitution of branded medicines for generic equivalents. In particular:

- a. Third party payors (“TPPs”) and pharmacy benefit managers (“PBMs”) use a variety of tools to steer patients to less expensive generic medicines. One of the most common tools that TPPs and PBMs use are drug formularies, which determine which prescription medicines a particular health plan covers, and how much the patient has to pay out-of-pocket for each medicine.<sup>84</sup> Academic research confirms that the difference in out-of-pocket costs between generic medicines and their reference branded medicines is effective in encouraging patients to switch to generic medicines once they become available.<sup>85</sup> In addition to formularies, TPPs and PBMs often steer patients to generic medicines by imposing requirement of prior authorization on branded medicines or requiring patients to try and fail a treatment with a generic medicine before the insurance plan will cover the use of the reference branded medicine.<sup>86</sup>

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<sup>80</sup> Karen A. Goldman et al., “Authorized Generic Drugs: Short-Term Effects and Long-Term Impact,” Federal Trade Commission Report, August 2011, pp. 1-153 at p. 17.

<sup>81</sup> Teva 2017 10-K, p. 5.

<sup>82</sup> Baeder Deposition, p. 416:9–11.

<sup>83</sup> Darius Lakdawalla and Tomas Philipson, “Does Intellectual Property Restrict Output? An Analysis of Pharmaceutical Markets,” *Journal of Law and Economics*, 55(1), 2012, pp. 151–187.

<sup>84</sup> Formularies typically organize drugs in tiers, with generic drugs on the lower tiers requiring lower patient co-payments and branded drugs on the higher tiers requiring higher patient co-payments, which can encourage patients to use less expensive generic drugs. See Kaiser Family Foundation and Health Research & Educational Trust, “Employer Health Benefits Annual Survey,” 2016, pp. 1-253 at pp. 172–173, 177.

<sup>85</sup> See, e.g., Douglas E. Mager and Emily R. Cox, “Relationship Between Generic and Preferred-Brand Prescription Copayment Differentials and Generic Fill Rate,” *The American Journal of Managed Care*, 13(6), 2007, pp. 347–352 at pp. 350–351. See also, Sachin Kamal-Bahl and Becky Briesacher, “How Do Incentive-Based Formularies Influence Drug Selection And Spending For Hypertension?,” *Health Affairs*, 23(1), 2004, pp. 227–236 at pp. 227–228, 231.

<sup>86</sup> See, e.g., Ernst R. Berndt, “The U.S. Pharmaceutical Industry: Why Major Growth in Times of Cost Containment?,” *Health Affairs*, 20(2), 2001, pp. 100–114 at pp. 102–103; Stanley S. Wallack, Dana Beth Weinberg, and Cindy Parks Thomas, “Health Plans’ Strategies to Control Prescription Drug Spending,” *Health Affairs*, 23(6), 2004, pp. 141–148 at pp. 141–142, 146.

- b. State generic substitution laws are the second major mechanism that promotes the use of generic medicines. Under these laws, pharmacies can substitute generic equivalents for the reference branded medicine unless the physician specifically prohibits generic substitution, usually by writing “dispense as written” on the prescription.<sup>87</sup>

49. In summary, Plaintiffs’ allegations that the Teva and Actavis Generic Defendants designed and implemented a sophisticated and deceptive marketing strategy” that “has had severe and far-reaching” consequences is not consistent with the data and deposition testimony. Specifically, Teva USA and Actavis Generic Defendants’ marketing efforts with respect to its generic opioid products was miniscule. In addition, data from IMS IQVIA show that the Teva Defendants’ branded opioid products’ market share in the Bellwether Counties was extremely small.

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<sup>87</sup> Ohio Rev. Code Ann. § 4729.38(B) (“Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug prescribed by its brand name may, subject to the following conditions, select a generically equivalent drug, or, in the case of a drug that is a biological product, select an interchangeable biological product”).